Index No: 22 -cv- ( )( )

United States District Court

SOUTHERN DISTRICT OF NEW YORK

DOUGLAS SCHOTTENSTEIN, MD AND SCHOTTENSTEIN PAIN AND NEURO, PLLC D/B/A NY SPINE

Plaintiff

–v–

UNITED STATES FOOD AND DRUG ADMINISTRATION, ROBERT M. CALIFF, M.D., ACTINGCOMMISSIONER OF THE UNITED STATES FOOD AND DRUG ADMINISTRATIONIN HIS OFFICIAL CAPACITY ONLY

Nominal Defendants

EDWARD L. CAPLA; JUDITH J. CAPLA, MD; TOMAS CAPLA, DDS; YOLANDA CAPLA; BRADLEY WASSERMAN, MD; ORTHOGEN INTERNATIONAL GMBH; PROF. DR. PETER WEHLING; NINA BREIDENBACH; PETER NIEDERAU; AND "JOHN DOE, JANE DOE & ABC CORP. 1-10"

Defendants,

VERIFIED COMPLAINT

RICHARD BRUCE ROSENTHAL, ESQ.
JEFFREY A. DONNER, ESQ.
CORY H. MORRIS, ESQ.

Attorneys for Douglas Schottenstein

TABLE OF CONTENTS

VERIFIED COMPLAINT

1. Plaintiffs Douglas Schottenstein, MD and Schottenstein Pain and Neuro, PLLC doing business as NY Spine, maintaining their principal office at 18 E. 48th Street, Suite 901, New York, NY 10017 (collectively "Plaintiffs" or "Plaintiff") bring this action through their attorneys to address an unapproved withdrawal, treatment and reintroduction of blood back into similarly situated persons deprived of the benefit of either a licensed medical profession or person properly trained by Defendant Orthogen International GMBH, an entity that has gone through great lengths to avoid oversight by the United States Food And Drug Administration, named herein to address imminent harm if not death to similarly situated persons seeking such treatment, mostly Plaintiffs' former patients who were, among other things, professional athletes.

2. Giving rise to federal questions under applicable laws and regulations as cited herein, Defendant Orthogen conspired with the Capla Defendants to evade the assertion of regulatory jurisdiction including investigation, testing and an approval process by the United States Food and Drug Administration over Regenokine, which engages in autologous procedures drawing blood from patients with inflammation from trauma or other causes, treating that blood with proprietary substances and processes and then reintroducing that blood, now a prepared drug, pharmaceutical or modality subject to regulation, through injection into the patient at the affected sites. The Defendants, individually and collectively, used interstate wire communications in furtherance of this scheme that was done to avoid the foregoing federal scrutiny and oversight.

3. Defendants, individually and collectively, devised a scheme to defraud the Plaintiff and others and used mail and wire to transfer and secret monies, some of which were unlawfully obtained.

4. Defendants, individually and collectively, engaged in various acts of fraud, knowing and willfully participated in a scheme with intent to defraud the Plaintiffs and others similarly situated in the use of a drug added to blood and reintroduced into the body.

5. In so doing, Capla Defendants, discussed further herein took monies that should have gone to Plaintiffs and distributed the money to other persons, persons that did not perform any medical service, and secreted profits from various government entities for, *inter alia,* unlicensed medical drug/treatments.

6. This relationship with Capla Defendants and Wasserman was both confidential and fiduciary, and proved to be highly beneficial and remunerative averaging about twelve-million (12) dollars a year from this single practice and roughly the same amount of money from the doctors who were similarly engaged and is thus Orthogen operates a multimillion dollar enterprise in the greater United States.

7. The Defendants, individually and collectively, all contributed to an enterprise using mail and wire to secret monies, administer an unlicensed medicine/drug that relies on the reintroduction of blood back into the patient's body, create unlawful profits and transfer monies to Orthogen while avoiding any meaningful regulation or United States Food and Drug Administration oversight.

PRELIMINARY STATEMENT

8. This is an action for declaratory relief against defendants United States Food and Drug Administration ("FDA") and against defendants Orthogen International GmbH ("Orthogen") to determine (1) whether Regenokine® is a drug, pharmaceutical or other modality subject to its administrative oversight and regulation through its Center for Biologics Evaluation and Research ("CBER"); (2) that in the interest and protection of public health and safety, the use of Regenokine® on patients in the United States must be stayed pending the decision of FDA as to whether or not investigation and testing of Regenokine® and the imposition of the process to thoroughly review Regenokine® to determine whether it is rejected as a drug, pharmaceutical or modality for the treatment of patients or approved with or without specific conditions or limitations; and (3) that the use of Regenokine® on any patient constitutes the practice of medicine under New York law, which practice must be licensed, thereby rendering a Regenokine® License to an individual not licensed to practice medicine nugatory and meaningless, *void ab initio*, and without force or effect.

9. This is also an action against defendant Orthogen, Professor Dr. Peter Wehling ("P. Wehling"), Nina Breidenbach ("Breidenbach") and Peter Niederau ("Niederau"), hereinafter, collectively the "Orthogen defendants," seeking injunctive relief, compensatory and exemplary damages, and a constructive trust arising out of the claims asserted herein for tortious interference with the economic relationship and advantage of plaintiffs with defendant Edward L. Capla ("Capla") as well as for fraud and deceit, and conspiracy to

defraud and exclude plaintiffs from a medical practice in which they owned at least 50%.

10. Furthermore, this is also an action against defendants Edward L. Capla ("Capla"), Judith J. Capla, MD ("J. Capla"), Tomas Capla, DDS ("T. Capla"), Yolanda Capla ("Y. Capla") and Bradley Wasserman, MD ("Wasserman"), hereinafter, collectively referred to as the "Capla defendants," seeking compensatory and exemplary damages and a constructive trust arising out of the claims asserted herein for fraud and deceit, breach of fiduciary duty and duty of loyalty, breach of contract, breach of the implied covenant of good faith and fair dealing, conversion and unjust enrichment.

JURY TRIAL DEMANDED

11. The Plaintiffs hereby demand a trial by jury on all issues so triable.

JURISDICTION

12. This Court has subject matter jurisdiction of this action pursuant to 28 U.S.C. Section 1331 in that this is a civil action that raises federal questions that arise under the Constitution, laws or treaties of the United States. Moreover, the pendent claims are wholly intertwined with the federal questions asserted herein such that neither can be fully resolved without reference to the other.

13. Venue is proper in the United States, in that Plaintiffs maintain their principal office herein, all Defendants do not reside in the same State and a substantial part of the events and omissions giving rise to the claims asserted herein occurred in this District and not at all in Germany.

VENUE

14. The United States District Court for the Southern District of New York is the appropriate venue for this action.

15. Venue is proper in this District under 28 U.S.C. § 1391 becauseOrthogen International GMBH sought to introduce a drug/treatment into the United States through Plaintiffs' practice and conspired with the named defendants in this action to, *inter alia*, administer the reintroduction of blood back into similarly situated persons deprived of United States Food And Drug Administration oversight and regulation.

THE PARTIES AND STATEMENT OF CASE

16. Plaintiff Douglas Schottenstein, MD is a medical doctor licensed to practice in both the States of New York and Florida, specializing in Neurology and Pain Management. He is Board Certified in both specialties placing him in a rare group of elite medical professionals that have achieved this double Board Certification.

17. Due to Dr. Schottenstein's high profile in the medical community and his frequent appearances in media to discuss professional issues, his professional activities garner attention.

18. Dr. Schottenstein operates his medical practice through plaintiff Schottenstein Pain and Neuro, PLLC doing business as NY Spine, which maintains its principal office at Suite 901, 18 East 48th Street, New York, NY 10017.

19. Defendant United States Food and Drug Administration ("FDA"), through its Center for Biologics Evaluation and Research ("CBER"), regulates biological products for human

use under applicable federal laws, including the Public Health Service Act, 42 U.S.C. Section 201 et seq. and the Federal Food, Drug and Cosmetic Act, 21 U.S.C. Section 1 et seq. The FDA and CBER protect and advance public health by ensuring that biological products are safe, effective and appropriately used.

20. As a vital part of the foregoing purposes, the FDA and CBER are responsible for regulatory oversight of the blood supply within the United States.

21. FDA promulgates and enforces standards for blood collection and for the manufacturing of blood products, including both transfusible and reintoductable components of whole blood, pharmaceuticals derived from blood cells or plasma, and related medical devices.

22. By characterizing Regenokine as a treatment program as opposed to a drug, Orthogen has deliberately avoided the FDA and CBER approval process, and in doing so have chosen monetary profit over the safety and welfare of the public, and, most specifically, the safety and welfare of the patients that undergo Regenokine in the belief that it is not a drug.

23. This state of affairs coupled with Orthogen's licensing of Regenokine to non-licensed practitioners posing as medical doctors poses a likely imminentand irreparable threat to the lives of American citizens exposed to this regime.

24. Plaintiffs are Regenokine Licensees expected by Orthogen to administer Regenokine to patients with inflammation and/or traumatic injury to principal joints and critical sites in their bodies, and have also been targeted by the Orthogen Defendants and the Capla Defendants due to their concerns regarding the unregulated and likely dangerous aspects of the

Regenokine® Program that poses an imminent threatwith irreparable harm to the health, safety and welfare of the public throughout the United States and within this District.

25. Orthogen International GmbH is a German corporation with offices located at Ernst-Schneider-Platz 1, 40212 Dusseldorf, Germany. Orthogen is the Licensor of an autologous treatment regimen known as the Regenokine® Program pursuant to which patients with specified injuries or conditions may be treated with the objective of reducing inflammation and promoting healing on an accelerated basis.

26. In its capacity as Licensor, Orthogen has made and continues to make appearances in the United States, including New York, both through in person visits by its representatives and numerous written and electronic communications and telephone calls to persons in the United States, including Dr. Schottenstein, regarding the licensing and promotion of the Regenokine® Program.

27. Commencing in or about 2012, Orthogen issued to plaintiff Dr. Schottenstein and defendant Capla a License with a two-year term to utilize the Regenokine® Program, which License was renewed in or about June, 2014. Thereafter, in or about July, 2014, the License was amended to be perennial requiring no further renewals, and having a term coextensive with the duration of the patents protecting the proprietary and confidential methods and knowledge on which the Regenokine® Program is based.

28. As amended, the Orthogen License issued to plaintiff Dr. Schottenstein and defendant Capla could only be terminated "for cause" as defined in the License Agreement.

29. Thereafter, on plaintiffs' information and belief, at some point, the Orthogen defendants commenced to conspire with the Capla defendants in order to continue to elude regulation and oversight by the FDA over Regenokine®. To do so, Orthogen utilized a high level of concealment under an impenetrable cloud of internal proprietary regulation, to which plaintiffs had expressed concerns.

30. Through this conspiracy, Orthogen also sought to interfere with and deny plaintiffs the benefits of their economic relationship with the Capla defendants, and to act fraudulently and deceitfully to cover up said conspiracy and prevent plaintiffs from taking action to challenge and remediate same.

31. Based upon Plaintiffs' information and belief, on or about March 24, 2020, Orthogen in conspiracy with the Capla defendants and with specific intent to do so, wrongfully terminated the perennial License for the Regenokine® Program issued to plaintiff Dr. Schottenstein and defendant Capla, not on any "for cause" basis, but on the sole basis that the License was not being renewed. At all times pertinent to this illegal action and the underlying conspiracy by and between the Orthogen defendants and the Capla defendants, Orthogen and the other Orthogen defendants knew that they were tortiously interfering with plaintiffs' economically advantageous relationship with the Capla defendants that would result in losses to plaintiffs in the tens of millions of dollars.

32. Within days after the discontinuance of the Regenokine® Program License Agreement with Schottenstein and Capla, Orthogen in furtherance of the aforesaid conspiracy entered

into a new Regenokine® Program License Agreement with defendants Wasserman and Capla.

33. After discontinuance of the Regenokine® Program License with Schottenstein, Orthogen directed persons in the United States to Wasserman and/or Capla for Regenokine®.

34. On information and belief, Orthogen was motivated to take these steps in order to avoid the likelihood of regulation of Regenokine® by the FDA and CBER as a drug or other regulated modality or device as a result of Plaintiffs' high profile arising from his extraordinary credentials, his reputation in medical circles and the media as an expert in the fields of neurology and pain management, his frequent consultations in broadcast and print media, and his expressed concerns over the absence of any effort by Orthogen to have Regenokine® officially reviewed.

35. Defendant Professor Dr. Peter Wehling ("P. Wehling"), maintaining an address with defendant Orthogen, is the founder and developer of the Regenokine® Program, and a principal stockholder in Orthogen AG, Orthogen's parent, with whom he has contracted in order to permit Orthogen to license and administer the Regenokine® Program. Wehling has had numerous contacts and communications with Dr. Schottenstein in the United States.

36. On plaintiffs' information and belief, in conspiracy with the other Orthogen defendants and the Capla defendants,Wehling actively and knowingly engaged in fraudulent and deceitful communications with Dr. Schottenstein with the specific intent to mislead Dr. Schottenstein, prevent him from learning of the foregoing conspiracy, and cause him to withhold action challenging the

License non-renewal and to remediate the damages willfully being caused.

37. In this regard, Wehling deliberately, fraudulently and deceitfully misinformed Dr. Schottenstein that the non-renewal of the License was merely the result of a change in Orthogen's internal policy to limit practice under theRegenokine® Program to German practitioners while Orthogen was engaging in discussions to sell all or a portion of the Regenokine® Program rights to third parties. Wehling also fraudulently and deceitfully misinformed Dr. Schottenstein that the License would be reissued to Capla and him promptly after the current negotiations were concluded.

38. Defendant Nina Breidenbach, maintaining an address with defendant Orthogen, is a former Managing Director of Orthogen and presently supervises and implements licensee training, adherence to operational criteria, reporting requirements, royalty payments and other licensee services within the Regenokine® Program.

39. At all relevant times, Breidenbach has physically travelled and continues to travel to New York City and other locations throughout the United States in relation to her responsibilities to the Regenokine® Program and to plaintiff Dr. Schottenstein as a Regenokine® Program Licensee .

THE CONSPIRACY AND EVASION OF U.S. REGULATION

40. On information and belief, Breidenbach actively conspired with the other Orthogen defendants and the Capla defendants with the express intent to interfere with plaintiffs' economically advantageous relationship with Capla, and

through fraudulent and deceitful actions and/or omissions to deprive plaintiffs of the revenues earned under that relationship.

41. As part of the foregoing conspiracy, Breidenbach signed and sent to Dr. Schottenstein and Capla the March 24, 2020 non-renewal notice thereby discontinuing the Regenokine® Program License Agreement issued to them.

42. On information and belief, Breidenbach joined in the conspiracy to disrupt the economically advantageous relationship that plaintiffs enjoyed with the Capla defendants, and thereafter participated in the fraudulent and deceitful conduct with the other Orthogen defendants to terminate that relationship and fulfill the objectives of the conspiracy by issuance of a new License to Wasserman and Capla.

43. Defendant Peter Niederau, maintaining an address with defendant Orthogen, is the current Managing Director of Orthogen. In furtherance of the foregoing conspiracy with the other Orthogen defendants and the Capla defendants, on August 3, 2022, Niederau signed and delivered a letter to Dr. Schottenstein refusing to provide any know-how or services under the Regenokine® Program, stating "that there is no valid licensing agreement between you [Dr. Schottenstein] and ORTHOGEN," and demanding that Dr. Schottenstein refrain from any offer of the Regenokine® Program to his patients and to immediately take other specifically designated actions to disassociate from the Program.

44. In preparing and sending this letter to Dr. Schottenstein, Niederau both advanced the conspiracy in which he had joined, acted knowingly with fraud and deceit, and fully ratified the conspiracy between and among the Orthogen defendants and the Capla defendants.

45. Defendant Edward L. Capla, maintaining an office address at c/o Bradley Wasserman, MD, 125 East 63rd Street, New York, NY 10065, on information and belief, holds a medical degree but on information and belief is not licensed to practice medicine. Nevertheless, Capla wrongly and unethically utilizes the title of "Doctor," thereby deliberately misinforming the public thereby causing members thereof to believe that he is a licensed medical professional when he is not.

46. Because he does not hold a medical license and cannot legally perform the duties required to participate as a Regenokine® Programtreatment provider, Capla cannot be a direct licensee of the Regenokine® Program.

47. In or about 2012, Capla was named as a subordinate Licensee under an agreement with Orthogen to participate in the Regenokine® Program, subject to the direction and supervision of plaintiff Dr. Schottenstein, the primary Licensee to which the License was granted. The initial License was for a 2-year term subject to renewal by Orthogen.

48. This initial License could be terminated by non-renewal for no specific reason at the expiration of the term or "for cause," at any time based upon the reasons set forth in the License agreement, itself. .

49. At the outset of the initial License term, Plaintiffs and Capla formed a mutually beneficial economic relationship through their agreement to operate under the License, pursuant to which plaintiff Dr. Schottenstein administered Regenokine® Program treatments to patients and Capla focused on reporting requirements and calculation of royalty payments. This agreement proved to be highly beneficial and remunerative, and the practice administering treatments to

patients under the Regenokine® Program grew exponentially to the point that the services of some of the other Capla defendants, that is Judith J. Capla, MD; Tomas Capla, DDS and Yolanda Capla, were utilized to handle laboratory work responsibilities.

50. The initial License was renewed in or about June, 2014 for an additional 2-year term, but promptly thereafter, in or about July, 2014, the License was modified by written Side Letter Agreement with Orthogen to have a perennial term "until the last of the REGENOKINE TREATMENT PATENTS have expired or the KNOW-HOW is no longer protected, whichever is later, unless earlier terminated as provided in this Article 10" [for cause].As a result of this modification, renewal of the License was no longer required, and the License could only be terminated for cause as delineated therein.

51. During the next six years, the Regenokine® Program practice within the relationship between plaintiffs and Capla grew to in excess of 3,500 patients and yielded distributions to plaintiffs of $6 million per year and a like amount to Capla with distributions to J. Capla, T. Capla and Y. Capla for their services.

52. On information and belief, at some point in this time frame, in violation of his fiduciary duty and agreementwith plaintiffs as partners, Capla and the other Capla defendants began to conspirewith the Orthogen defendants to exclude plaintiffs from the right to practice under the Regenokine® Program License.

53. In doing so, the Capla Defendants acted with fraud and deceit deliberately shielding their activities from plaintiffs and making statements both verbally and in writing calculated to mislead plaintiffs thereby causing Dr. Schottenstein to believe

that all was in order within the partnership with Capla. Orthogen was complicit in and engaged in such fraud by participating in and not informing Schottenstein of these negotiations.

ACTS IN FURTHERANCE OF THE CONSPIRACY; THE POISONING OF DR. SCHOTTENSTEIN

54. In or about mid-January, 2020, plaintiff Dr. Schottenstein became extremely ill with a life threatening condition requiring hospitalization, intensive care and kidney dialysis administered on an emergent basis in order to remedy this condition. It appears that this condition arose as a result of Dr. Schottenstein ingesting antifreeze surreptitiously added to his food or drink. There was no reason, whatsoever, for antifreeze to be stored in the NY Spine office, but an open and partially used container of antifreeze was found in the NY Spine storage room when Dr. Schottenstein returned to the office.

55. Prior to Dr. Schottenstein's affliction with his sudden, severe and life threatening condition, defendant Capla and the other Capla Defendants had full and unfettered access to both the NY Spine offices and Dr. Schottenstein.

56. During the time that Dr. Schottenstein was hospitalized, defendant Bradley Wasserman, MD, defendant Capla's brother-in-law, was brought into the NY Spine office to administer Regenokine® Program treatments to Dr. Schottenstein's patients without Dr. Schottenstein's knowledge or consent.

57. On information and belief defendants Judith J. Capla, MD is a licensed physician, who maintains an office at 530 1st

Avenue, New York, NY 10016 and purports to specialize in Allergy and Immunology as well as Pediatrics.

58. Judith J. Capla, MD ("J. Capla") is defendant Capla's mother. At relevant times to this action, defendant J. Capla was an independent contractor providing laboratory services to the plaintiffs and defendant Capla.

59. On information and belief, defendant J. Capla conspired with the other Capla defendants to exclude plaintiffs from the right to practice under the Regenokine® Program License. In doing so, she acted in violation of her fiduciary duty and duty of loyalty to plaintiffs, and with fraud and deceit deliberately shielding her activities from plaintiffs and making statements calculated to mislead plaintiffs thereby causing Dr. Schottenstein to believe that all was in order within the agreement with defendant Capla.

60. On information and belief, Tomas Capla, DDS ("T. Capla") is a licensed dentist, who maintains an office at 2500 Johnson Avenue, Riverdale, NY 10463. He is defendant Capla's father.

61. At relevant times to this action, defendant T. Capla was an independent contractor providing laboratory services to plaintiffs and defendant Capla. On information and belief, defendant T. Capla conspired with the other Capla defendants to exclude plaintiffs from the right to practice under the Regenokine® Program License.

62. In doing so, T. Capla acted in violation of his fiduciary duty and duty of loyalty to plaintiffs, and with fraud and deceit deliberately shielding his activities from plaintiffs and making statements calculated to mislead plaintiffs thereby causing Dr. Schottenstein to believe that all was in order within the agreement with defendant Capla.

63. On information and belief, Yolanda Capla ("Y. Capla") maintains an office address at c/o Bradley Wasserman, MD, 125 East 63rd Street, New York, NY 10065. She is defendant Capla's wife.

64. At relevant times to this action, defendant Y. Capla was an independent contractor providing laboratory services to plaintiffs and defendant Capla.

65. On information and belief, defendant Y. Capla conspired with the other Capla defendants to exclude plaintiffs from the right to practice under the Regenokine® Program License.

66. In doing so, Y. Capla acted in violation of her fiduciary duty and duty of loyalty to plaintiffs, and with fraud and deceit deliberately shielding her activities from plaintiffs and making statements calculated to mislead plaintiffs thereby causing Dr. Schottenstein to believe that all was in order within the agreement with defendant Capla.

67. On information and belief. Bradley Wasserman, MD ("Wasserman") is a licensed physician, who maintains an office at 125 East 63rd Street, New York, NY 10065 and purports to specialize in orthpaedic surgery and sports medicine.

68. Wasserman is defendant Capla's brother-in-law. During the time that Dr. Schottenstein was hospitalized on an emergent basis, defendant Wasserman was brought into the NY Spine office by defendant Capla to administer Regenokine® Program treatments to Dr. Schottenstein's patients without Dr. Schottenstein's knowledge or consent.

69. On information and belief, defendant Wasserman conspired with the other Capla defendants to exclude plaintiffs from the right to practice under the Regenokine® Program License.

70. In doing so, Wasserman acted in violation of his fiduciary duty and duty of loyalty to plaintiffs, and with fraud and deceit deliberately shielding his activities from plaintiffs and making statements calculated to mislead plaintiffs thereby causing Dr. Schottenstein to believe that all was in order within the agreement with defendant Capla.

71. Defendants John Doe, Jane Doe and ABC Corp. 1-10 are fictional defendants intended to cover other wrongdoers in this matter, whose identities are presently unknown, but who may become known in the course of discovery hereunder, and whom plaintiffs reserve the right to implead as defendants in this action.

FACTS RELEVANT TO THE PLAINTIFF'S CLAIMS

72. In or about mid-2012 defendant Orthogen designated plaintiff Dr. Schottenstein and defendant Capla as Licensees under the Regenokine® Programfor a 2-year term.

73. Since Capla was not licensed to practice medicine, he could not treat patients and was designated Licensee No. 2. In that capacity, Capla was subject to the supervision of Dr. Schottenstein, a licensed medical practitioner, designated as Licensee No. 1, who acted as the sole provider for patient treatment under the License and was responsible for same.

74. In 2014, the License was renewed for a 2-year period, but that renewal was promptly followed by a Side Letter that granted Dr. Schottenstein and Capla a perennial License that did not require renewal, with a term coincident with the ultimate patent expiration for the Regenokine® Program, and could be terminated only upon a for cause basis.

75. As Licensee No. 1, Dr. Schottenstein was in charge of patient treatment. Since Capla was not authorized to treat patients, he oversaw the reporting and royalty payment calculations to Orthogen.

76. The Regenokine® Program treatment practice conducted through plaintiff NY Spine at its offices in New York City and also in Miami, Florida rapidly grew to in excess of 3,500 patients,yielding both Dr. Schottenstein and Capla approximately $6 million per year.

77. As the Regenokine® Program treatment practice grew, defendants, and co-conspirators, J. Capla, T. Capla and Y. Capla were brought into this practice as independent contractors to prepare the laboratory work needed to conduct the Regenokine® Program treatments.

78. Capla paid roughly two-thirds of his compensation to defendants J. Capla and T. Capla, his parents, in order to shield this income and thereby avoid explanation as to why he qualified for this level of compensation based upon the ministerial work that he was producing within the Regenokine® Program practice.

79. On information and belief, defendants J. Capla and T. Capla deposited the portion of the compensation paid to them but allocated to defendant Capla into a joint account in which Capla was a signatory able to withdraw this compensation.

80. The Regenokine® Program treatment practice continued in the foregoing manner until in or about early 2020.

81. In early to mid-January, 2020, Dr. Schottenstein suddenly became ill with a life threatening condition that required immediate hospitalization, intensive care and kidney dialysis.

82. The doctors attending to Dr. Schottenstein in hospital stated that his condition was consistent with having ingested ethylene glycol, the active ingredient in antifreeze.

83. Up until this time, Dr. Schottenstein had been in good health, and had never had an issue with his kidneys.

84. Dr. Schottenstein has had no such problem since his recovery from this incident.

85. There is absolutely no reason for antifreeze to be kept in storage in a medical office.

86. Nevertheless, upon Dr. Schottenstein's recovery and return to the NY Spine office at the end of January, 2020, Dr. Schottenstein did discover an open, partially used container of antifreeze in the store room.

87. Dr. Schottenstein did not purchase the antifreeze and was not previously aware of this substance being in the NY Spine office.

88. When Dr. Schottenstein returned to the NY Spine office following his hospitalization, he also found that defendant Wasserman had been hired by Capla as an independent contractor, and was treating Dr. Schottenstein's patients without his knowledge or consent.

89. Prior to Dr. Schottenstein's life threatening illness, the Capla defendants had free and unfettered access to the NY Spine office and to Dr. Schottenstein's physical presence.

90. Until just prior to Dr. Schottenstein's illness, two NY Spine employees subsequently found to be faithless, and having stolen through unauthorized wire transfers and other means over $2.5 million from Dr. Schottenstein, also enjoyed this

unfettered access to the NY Spine office and Dr. Schottenstein's physical presence.

91. Dr. Schottenstein had terminated these two employees without knowledge of their theft in or about early January, 2020.

92. Dr. Schottenstein has filed a Complaint against these faithless employees in Federal Court in the Southern District of New York.

93. Included in Dr. Schottenstein's filing on information and belief is that these faithless employees were involved in causing Dr. Schottenstein to ingest antifreeze in his food or drink at the office.

94. In their voluntary disclosures in that matter in the Southern District of New York, these defendant faithless employees have listed defendant Capla as a person with knowledge potentially anticipated to testify at the time of trial. This link between these faithless employees and Capla raise the issue as to whether Capla played a role in some of the bad acts engaged in by these employees, including the deliberate poisoning of Dr. Schottenstein.

95. On information and belief, there came a time when the Capla defendants conspired amongst themselves and with Orthogen and the Orthogen defendantsto exclude plaintiffs from the right to practice under the Regenokine® Program License.

96. In doing so, both the Orthogen defendants and the Capla defendants acted with fraud and deceit deliberately shielding their activities from plaintiffs and making statements calculated to mislead plaintiffs thereby causing Dr. Schottenstein to believe that all was in order within the agreement with Capla.

97. In acting in this manner, the Orthogen defendants well knew that they were acting tortiously to interfere with the highly advantageous economic relationship by and between plaintiffs and Capla, and that their actions further constituted a breach of the fiduciary duties they owed to plaintiffs.

98. The Capla defendants through this conspiracy with the Orthogen defendants breached the agreement by and between Dr. Schottenstein and Capla as well as the implied covenant of good faith and fair dealing and their respective duties of loyalty to plaintiffs.

99. On or about March 24, 2020, defendant Orthogen acting through defendant Breidenbach, then Managing Director, and fully supported by defendant Wehling, issued a letter to Dr. Schottenstein and defendant Capla advising that the License under the Regenokine® Program was to be terminated by May 31st, 2020 on the basis of non-renewal in accordance with the June 1st, 2014 License Agreement.

100. The March 24, 2022 letter did not refer to any for cause basis for Dr. Schottenstein's termination.

101. On information and belief this March 24, 2020 letter was issued to achieve the purpose of the conspiracy between the Orthogen defendants and the Capla defendants.

102. Moreover, although not mentioned in the March 24, 2020 letter, on information and belief, the arrangement to issue a newRegenokine® ProgramLicense to defendant Capla and defendant Wasserman to the exclusion of plaintiffs had already been agreed upon.

103. The March 24, 2020 letter constituted an illegal action by defendant Orthogen, issued in breach of the controlling Side

Letter Agreement dated July 9, 2014 but expressly related back to and effective as of June 1, 2014, and was void *ab initio*.

104. Shortly after the receipt of the March 24, 2020 letter defendants Capla and Y. Capla sent Dr. Schottenstein the following text message after Dr. Schottenstein, still unknowledgeable about the conspiracy and the arrangement engineered by Orthogen and Capla, suggested that they continue their practice of autologous remedies outside of the Regenokine® Program using methodologies that did not incorporate or rely upon the Regenokine® Know-How:

> We wanted to express our deep gratitude andappreciation to you for all you have done forus and Regenokine. What we have accomplishedas a team is remarkable and without you it wouldnever have happened. You're an amazing personto work with and your tireless effort and care hasmade our jobs so much easier and more enjoyable.Your time, support, and cooperation we value a lot. Your exemplary work approach is unsurpassable.Much of the success of our team is because we allhad the same mentality – hard work leads to success. Thank you from the bottom of our hearts for being agreat colleague and never letting us settle for anythingless than best. We appreciate your offer but we decided to move forward on a different path. Wishing you only the best forever and lots of continued success in your practice. I would like to come on Friday evening when you are done with patients to pick up our belongings. Let me know if this works.

105. Thereafter, Dr. Schottenstein was informed by defendant Wehling, the founder of the Regenokine® Program treatments, that the termination reflected a change in Orthogen's corporate policy pursuant to which Orthogen was limiting its

Regenokine® Program licensing to practitioners in Germany as it proceeded to negotiate the sale of the program rights.

106. Defendant Wehling further informed Dr. Schottenstein that as soon as the Regenokine® rights were sold, Dr. Schottenstein would be offered an opportunity to relicense his Regenokine® practice.

107. These statements made to Dr. Schottenstein by defendant Wehling were outright lies calculated to cover up Orthogen's fraudulent, deceitful and tortious conduct.

108. The foregoing communications from defendants Capla and Y. Capla and defendant Wehling to Dr. Schottenstein were fraudulent and deceitful, and solely intended to convince Dr. Schottenstein that nothing untoward had occurred and to deter him from taking any formal action to challenge the failure to renew his License.

109. As an honest and trusting person, not disposed to suspicion of bad acts on the part of those with whom he deals, and relying upon the communications that he received from defendants, which subsequently proved to be intentionally misrepresented, fraudulent and deceitful, Dr. Schottenstein initially cooperated in suspending his Regenokine® practice.

110. In the following months, however, Dr. Schottenstein repeatedly sought to re-establish his License with Orthogen without success.

111. In the interim, however, Dr. Schottenstein learned that Orthogen had entered into a new License agreement with defendants Wasserman and Capla.

112. In or about mid-2022, Dr. Schottenstein assigned to legal counsel the task to review the non-renewal of his

Regenokine® License and defendant Orthogen's issuance of a new License to defendants Wasserman and Capla.

113. Upon review of the License documentation, it became apparent that the July, 2014 Side Letter Agreement had created a perennial License no longer subject to renewal at 2-year intervals and terminable only for cause. On that basis, it was clear that the March 24, 2020 termination notice was void *ab initio* and Dr. Schottenstein's License had never been terminated.

114. On or about July 28, 2022, and then again on August 3, 2022, Dr. Schottenstein communicated with defendant Orthogen requesting the reinstatement of his License and all benefits to which he was entitled to thereunder.

115. On August 3, 2022, defendant Peter Niederau, the current Managing Director of defendant Orthogen, joined the conspiracy and continued Orthogen's tortious and deceitful conduct by issuing a letter to Dr. Schottenstein denying his requests and stating, "In light of the fact that there is no valid licensing agreement between you and ORTHOGEN, we request for you to refrain from any offer of the Regenokine® Program to your patients and to immediately take the website 'www.regenokineperformance.com' offline as well as seize (sic; cease) all public relations actions related to or in context of [the] Regenokine® Program. Furthermore, from our point of view 'www.regenokineperformance.com' website and its content is in violation of ORTHOGEN IP rights (Trademark, Patents, Know-How rights) and may violate at the same time US-laws." The Niederau letter further threatened Dr. Schottenstein that Orthogen's "attorneys will approach you in the upcoming days to substantiate our legal claims."

116. In immediate response to the Niederau letter, on August 3, 2022, counsel for Dr. Schottenstein issued a letter to defendant Niederau baldly stating that his position is in error, and that he needed to put Orthogen's attorneys in contact with legal counsel for Dr. Schottenstein.

117. Realizing that their scheme had now been uncovered, on August 8, 2022, Klaus Wehling, who purports to be a legal counsel for defendant Orthogen communicated by e-mail conceding that Article 2 of the July, 2014 Side Letter Agreement "provides that Dr. Schottenstein is in principle granted a contract term until 2030 (patent term) Thus, it appears that the contract cannot be terminated without cause."

118. In a subsequent e-mail, Klaus Wehling stated, "the termination of the License Agreement in 2020 was invalid because ORTHOGEN's 2014 License Agreement in conjunction with the 2014 Supplemental Agreement provided that the term of the agreement should run until the end of the patent or know-how term (cf. Art. 2 of the Supplemental Agreement)….There was therefore agreement among all parties that the current contract had not been terminated and is therefore still valid."

119. These statements made by Klaus Wehling constitute an admission binding defendant Orthogenthat the Schottenstein License was never terminated even though the actions of Orthogen destroyed the economically advantageous relationship of plaintiffs with defendant Capla and their income therefrom, thereby precipitating Dr. Schottenstein's loss, at that time, of two years of Regenokine® revenue approximating $12 million.

120. Moreover, since the License's perennial term would extend for at least eight (8) more years through the year 2030, Dr. Schottenstein continues to lose revenue, and is at risk of losing an additional $48 million even before an upward adjustment of that loss calculation for additional growth in the practice, inflation and other applicable factors.

121. Recognizing that Orthogen's unjust position had literally cost Dr. Schottenstein the enormous losses he sustained, Klaus Wehling promptly proposed that Dr, Schottenstein would be identified as an expert in Regenokine® treatments, prominently featured on what he described as a universal landing page, and receive referrals of Regenokine® patients on an exclusive basis in the greater New York and Miami, Florida areas.

122. From the original License issuance in 2012 up to the time of the alleged termination in March, 2024, Dr. Schottenstein had received all of his Regenokine® patients from referrals by Orthogen.

123. Understanding that Dr. Schottenstein's License extended through 2030 and possibly longer should Orthogen continue to develop innovations for Regenokine® protectable by patent, plaintiffs decided to attempt to mitigate their damages through the promise of exclusive referrals without waiving any of their other remedial alternatives.

124. Nevertheless, despite Dr. Schottenstein undergoing updated training on the know-how in mid-September, 2022 and passing audits of his laboratory facilities and materials in the same time frame, no patient referrals from defendant Orthogen were forthcoming.

125. In response to communications from and on behalf of plaintiffs seeking patient referrals, Klaus Wehling countered with statements that there were irregularities in the reporting and royalty payment calculations under the 2014 License prior to the March 24, 2020 letter announcing non-renewal.

126. No such complaint was ever provided to Dr. Schottenstein prior to the illegal termination notice of March 24, 2020 that proceeded solely on a failure to renew, which was not applicable, and not on any for cause basis. Moreover, these alleged irregularities in reporting and royalty payments are alleged to have started in 2017, but the illegal termination letter did not issue until three years later in 2020.

127. In that three year period, Orthogen never communicated to Dr. Schottenstein that such problems existed, not once, even though Dr. Schottenstein was Licensee No.1 and thereby responsible for the supervision of Capla and all activity conducted under the License.

FACTS RELEVANT TO THE COVER UP, EQUITABLE RELIEF REQUESTED AND IMMINENT HARM

128. The fact that the Orthogen defendants actively misrepresented to Dr. Schottenstein the reason for the non-renewal, while going behind Dr. Schottenstein's back to enter into a substitute License Agreement with Capla, a non-doctor and the known likely wrongdoer in the alleged misreporting and under-paymentsof royalties, and his brother-in-law, defendant Wasserman, who had virtually no experience in autologous treatment protocols or pain management, highlight the bad faith, deceit, fraud, conspiracy and tortious interference by Orthogen and its principal actors.

129. In an e-mail dated November 7, 2022, Klaus Wehling at last partially addressed the issue of referrals as follows:

> As for referrals, ORTHOGEN can't say much about them. In the past, ORTHOGEN has not received any patient inquiriesfrom patients, so ORTHOGEN could never make any recommendation here. As far as the future is concerned, ORTHOGENwould – in case of a corresponding request – name the LICENSEES that offer theRegenokine® Program in the requested area(i.e., e.g. USA). Thus, there would be neither a preference nor aDisadvantage of any physician from ORTHOGEN. In any case,Every patient will look at the homepages of the offering physicians on the Internet and decide who to go to.

130. Klaus Wehling's statement in this regard was not only wholly inaccurate regarding Dr. Schottenstein's referral experience from Orthogen during the period from 2012 to 2020, but was also an outright lie.

131. Dr. Schottenstein had been informed by a number of his prior Regenokine® patients that they had been referred by Orthogen personnel, including defendant Niederau, to defendant Wasserman.

132. Contrary to Klaus Wehling's misrepresentation, Orthogen was referring former patients of Dr. Schottenstein to Wasserman for Regenokine® treatments while Dr. Schottenstein's License had not been cancelled, the patients being referred to defendant Wasserman were Dr. Schottenstein's patients, and defendant Orthogen was actively denying and covering up the referral practices in which it was presently engaged.

133. On November 10, 2022, plaintiff Dr. Schottenstein, disgusted with the lies, deceit, fraudulent conduct, tortious interference and conspiracy engaged in by the Orthogen defendants, addressed an e-mail to Klaus Wehling, defendant Breidenbach and defendant Peter Wehling demanding in blunt language that they restore to plaintiffs the Regenokine® Program practice that defendant Orthogen had tortiously taken away.

134. In response, by letter dated November 28, 2022 from legal counsel, Orthogen, first contended that the March 24, 2020 letter effectively terminated Dr. Schottenstein's License, a position that wholly ignores the admissions binding Orthogen that the Schottenstein License was never terminated and had been fully reinstated, then asserted that the reinstated License was terminated once again, this time for cause.

135. In that letter dated November 28, 2022, defendant Orthogen through its legal counsel threatened to commence litigation against plaintiffs in the court of Dusseldorf, Germany. Plaintiffs seek injunctive relief from this court to stay defendant Orthogen and the other Orthogen defendants from commencing such litigation in Germany, considering that this case includes the FDA for declaratory relief of the underlying federal question common to all the claims asserted as well as the Orthogen defendants and the Capla defendants comprising all of the parties needed to resolve the claims set forth hereunder, and where this matter addresses claims based upon tortious interference, fraud and deceit, breach of fiduciary duty, breach of the duty of loyalty, conspiracy, an accounting, unjust enrichment and constructive trust to remedy the wrongful acts that occurred within the jurisdiction of this Court.

136. The foregoing facts raise clear inferences that Orthogen issued the March 24, 2020 termination notice to Dr. Schottenstein not due to oversight or mistake, but with an intention evade federal regulation of Regenokine® andto tortiously interfere with the economically advantageous partner relationship with Capla that can no longer be ignored.

137. Orthogen was part of the conspiracy with Capla, Wasserman and the other Capla defendants to wrongly deprive plaintiffs of the benefits of the SchottensteinRegenokine® Program License, which conspiracy could not succeed in the absence of Orthogen's tortious interference with the Schottenstein-Capla agreement by wrongfully and illegally issuing the March 24, 2020 notice of termination on the basis of a failure to renew.

138. In this process, Orthogen and the other Orthogen defendants engaged in fraudulent and deceitful activities designed to both evade federal regulatory jurisdiction and hurt Dr. Schottenstein economically and by undermining his reputation.

139. The Orthogen defendants engaged in fraud and deceit to gain Dr. Schottenstein's cooperation with their nefarious ends, and when given the chance to restore Dr. Schottenstein's Regenokine® practice, they actively worked against him in favor of Capla and Wasserman then deliberately lied to conceal it.

140. The conduct of the Orthogen defendants as set forth in this Complaint is and continues to be scurrilous and outrageous meriting both compensatory and punitive damages in the millions of dollars.

141. In violation of his fiduciary duty and agreement with plaintiffs as partners, Capla and the other Capla defendants,

who also violated their duty of loyalty to plaintiffs, began to conspire with the Orthogen defendants to exclude plaintiffs from the right to practice under the Regenokine® Program License held by Dr. Schottenstein.

142. In doing so, they also acted with fraud and deceit, breached their fiduciary duty , breached the agreement between plaintiffs and Capla, and entered into a conspiracy by untruthfully informing plaintiffs they intended to undertake a real estate opportunity, and withheld from plaintiffs the material information that they had negotiated a substitute Regenokine® Program License to be issued to Wasserman and Capla, andunder which they intended to exclusively operate the Regenokine® Program practice in which Dr. Schottenstein held an equal, if not exclusive, interest.

143. In this manner, Capla and the Capla defendants deliberately shielded their activities from plaintiffs thereby causing Dr. Schottenstein to believe that all was in order within the agreement with Capla.

144. As a result, of their willful, deliberate and outrageous conduct, Capla, Wasserman and the other Capla defendants have been unjustly enriched to the detriment of plaintiffs in taking over and converting the operational, property and revenue interests and cash flow from theRegenokine® Program practice they presently operate, and to which plaintiffs claim at least a 50% interest together with claims for prior compensatory damages incurred, future compensatory damages to be incurred, and punitive damages arising from the scurrilous and outrageous conduct of these defendants.

145. Plaintiffs are entitled to establish a constructive trust over all assets, patient lists, treatment records and earnings of Capla, Wasserman and the other Capla defendants derived from

theRegenokine® Program practice, in which they have and continue to be wrongly engaged.

146. Defendant Orthogen has failed or refused to qualify to do business in New York. Additionally, to plaintiffs' information and belief, neither defendant Orthogen nor the other Orthogen defendants maintain assets within the State of New York sufficient to satisfy the monetary claims asserted against them herein.

147. On information and belief, plaintiffs assert that defendant Orthogen maintains an automatic transfer agreement and arrangement with its parent company, Orthogen AG, under which funds received by defendant Orthogen are immediately transferred to Orthogen AG, thereby creating additional unwarranted obstacles to the satisfaction of any judgment awarded to plaintiffs against the Orthogen defendants in this action.

148. Furthermore, the Orthogen defendants have exhibited a pattern of fraudulent, deceitful and otherwise outrageous tortious conduct as delineated in this Complaint giving rise to a high probability of compensatory and punitive damages being found against them.

149. In light of the foregoing, plaintiffs are further entitled to establish a constructive trust over all funds derived from the aforesaid Capla-WassermanRegenokine® Program practice and/or any other such practice located within New York State that would otherwise be payable to defendant Orthogen as royalties or other fees in order to maintain these assets of the Orthogen defendants within the jurisdiction of this Court to satisfy the claims asserted against it herein.

DECLARATORY JUDGMENT CLAIMS
DECLARATORY JUDGMENT AGAINST DEFENDANT ORTHOGEN INTERNATIONAL GMBH AND DEFENDANT UNITED STATES FOOD AND DRUG ADMINISTRATION

150. Plaintiffs repeat the allegations set forth in the above paragraphs and incorporate them by reference in this Count as if set forth at length herein.

151. Defendant Orthogen International GmbH ("Orthogen") is the international Licensor and distributor of Regenokine®, which it identifies as a treatment program designed to reduce inflammation and promote healing in various joints of the body, including the spine, knees and shoulders.

152. Orthogen takes great pains to differentiate Regenokine® from a drug that is regulated by Defendant United States Food and Drug Administration ("FDA").

153. Orthogen licenses and distributes Regenokine proprietary methods and procedures, which it identifies as "Know How," throughout the United States including, but not limited to the States of New York, Florida and California.

154. Orthogen has deliberately constructed a scheme built into its License Agreement to elude regulation and oversight by the FDA through a high level of Regenokine® concealment under an impenetrable cloud of internal proprietary regulation.

155. Orthogen Licensees can neither publicly discuss nor make any reference to Regenokine®in the absence of an advance submission to and approval by Orthogen's trademark and patent counsel located in Washington, D.C. in order to prevent any substantive disclosure that could trigger the imposition of regulatory measures or spawn competitors utilizing the "Know How.".

156. Regenokine involves an autologous procedure whereunder blood is drawn from the patient, treated with various proprietary substances and processes, and then re-introduced by injection back into the patient at the specific sites under treatment.

157. On information and belief, Orthogen has never sought or made submission to the FDA to determine whether or not Regenokine®is subject to regulatory review, administrative control and/or investigation, testing and the process for approval by the FDA.

158. Regenokine® is wholly elective.

159. Regenokine® is neither used nor intended as a last chance remedy for terminal patients facing the inevitable that are desperate for any answer and who are therefore prepared to assume any risk.

160. To the contrary, Regenokine® is offered at a high price on a cash only basis, is not reimbursable by health insurance, and is thereby shielded from questioning and attention that could result in regulation.

161. Orthogen does not advertise Regenokine®, but markets it through a detailed and developed system fueled by word of mouth among elite professional athletes and other wealthy patrons that need or otherwise desire to accelerate healing from physical trauma or inflammation arising from other causes. As such, these candidates for treatment under Regenokine®anticipate that they will incur no significant risk thereunder.

162. In this environment, it is highly likely that the representations made by Orthogen and its Regenokine®, licensees are overstated and misleading.

163. Defendant Orthogen, however, has licensed Regenokine in the United States to one or more individuals that are not licensed to practice medicine.

164. Defendant United States Food and Drug Administration ("FDA"), through its Center for Biologics Evaluation and Research ("CBER"), regulates biological products for human use under applicable federal laws, including the Public Health Service Act, 42 U.S.C. Section 201 et seq. and the Federal Food, Drug and Cosmetic Act, 21 U.S.C. Section 1 et seq. and regulations promulgated thereunder.

165. The FDA and CBER protect and advance public health by ensuring that biological products are safe, effective and appropriately used and stored.

166. As a vital part of the foregoing purposes, the FDA and CBER are responsible for regulatory oversight of the blood supply and the use, storage and treatment of blood within the United States.

167. In this regard FDA promulgates and enforces standards for blood collection, testing, and for the manufacturing and storage of blood products, including both transfusible and reintroductable components of whole blood, pharmaceuticals derived from blood cells or plasma, and related medical devices.

168. Federal regulations require among other standards that a person be free from and avoid any disease transmissible by blood transfusion or reintroduction, in so far as can be determined by health history and examination as well as the way in which blood is treated, stored and administered. Donors and recipients are required to be informed about potential risks and are further required to answer questions

about factors that may have a bearing on the safety of their blood and its subsequent administration.

169. FDA has recently required investigation, testing, and a rigorous approval process for other autologous procedures, namely two blood tests, Guardant360 CDx and Foundation One Liquid CDx, known as liquid biopsies, intended to guide treatment decisions for people with cancer. *See*, **Exhibit 1**, *FDA Approves Blood Tests That Can Help Guide Cancer Treatment*, US Gov. (December 26, 2022); accessible at:https://www.cancer.gov/news-events/cancer-currents-blog/2020/fda-guardant-360-foundation-one-cancer-liquid-biopsy.

170. The FDA regulatory process regarding these procedures resulted in the subject tests being approved for only certain cancers, and, in regard to the specified cancers only, these procedures can be used to guide the selection of a targeted cancer therapy.

171. The FDA also played a critical role in bringing to light the Theranos scandal engineered by its CEO Elizabeth Holmes and its Chief Operating Officer Sunny Balwani, when it ruled that nanotainers the company created to collect blood were an "unapproved" medical device.

172. Theranos had claimed it would revolutionize blood testing with technology that could analyze tiny amounts of blood to diagnose a wide range of medical conditions which resulted in Theranos entering into mega deals with Walgreens and Safeway for the sale and distribution of its Edison testing device. The device did not work causing Theranos to rely upon blood testing that could not be validated and to void as inaccurate testing results that questioned the capabilities of the device without disclosure resulting in a "massive fraud" subsequently prosecuted. *See,***Exhibit 2**, Danielle Kirsh,

Former Theranos lab director takes the stand, says Elizabeth Holmes was 'nervous' amid blood test inaccuracy concerns, Mass Device (September 27, 2021), last accessed on December 26, 2022: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/changes-approved-application-biological-products-human-blood-and-blood-components-intended.

173. By characterizing Regenokine®, as a treatment program as opposed to a drug, Orthogen has deliberately avoided the FDA and CBER approval process.

174. Orthogen has chosen monetary profit over the safety and welfare of the public, and, most specifically, the safety and welfare of the patients that undergo Regenokine® in the belief that it is not a drug.

175. Plaintiffs are Regenokine®, Licensees expected by Orthogen to administer Regenokine®, to patients with inflammation and/or injury to principal joints and critical sites in their bodies. Plaintiff Douglas Schottenstein, MD, a Regenokine®, Licensee, is also a licensed physician in the States of New York and Florida and is Board Certified in both Neurology and Pain Management. Plaintiff NY Spine is the entity through which Dr. Schottenstein engages in his medical practice and is also licensed by Orthogen to administer Regenokine® to his patients.

176. Plaintiffs are concerned that Orthogen has eluded FDA and CBER oversight and regulatory investigation, testing and approval to the likely detriment and imminent irreparable harm of their patients.

177. Plaintiffs are aware that FDA and CBER regulate the collection of blood and blood components used for transfusion and re-intoduction or the manufacture of pharmaceuticals

derived from blood and blood components, such as clotting factors, storage containers, storage procedures and establishing standards for the products themselves.

178. FDA further regulates related products such as cell separation devices, blood collection containers and other screening tests that are used to prepare blood products to ensure safety.

179. Under Title 21 of the Code of Federal Regulations 640.120, the Director, Center for Biologics Evaluation and Research has direct administrative and regulatory oversight regarding blood, blood components and/or blood products. Both licensed and unlicensed blood establishments must submit to this administrative and regulatory oversight under 21 CFR 601.12. *See*, **Exhibit 3**, Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture, December, 2014, Final Guidance.

180. In the absence of FDA and CBER regulation, investigation, testing and consideration for approval and the establishment of relevant conditions on which such approval might be based or the rejection of Regenokine®, as a drug product for the treatment of patients, Plaintiffs have significant and abiding concerns for the safety and welfare of their patients and members of the public, generally, all of which likely face imminent injury and irreparable harm.

181. As a result of Plaintiff's expression of their concerns to Orthogen, it has taken retaliatory measures against Plaintiffs attempting to terminate Plaintiffs' Regenokine®, License.

182. Plaintiffs maintain standing under this Count both as a result of their concerns for their patients and as medical

professionals sworn to do no harm for the general safety and welfare of the general public, and as targets of Orthogen's attempt to terminate their Regenokine®, License by reason of their concerns.

183. Plaintiffs contend that Regenokine®, is not merely a treatment method, but is a drug or other regulated substance subject to regulation, investigation, testing and approval or rejection for use under FDA and CBER protocols that are mandated for the safety of the general public and the individual patients that seek Regenokine®, for their inflammation, pain and needs for healing from traumatic and other circumstances.

184. The foregoing applicability of the Public Health Service Act, 42 U.S.C. Section 201 et seq. and the Federal Food, Drug and Cosmetic Act, 21 U.S.C. Section 1 et seq. and associated federal regulations thereunder to the facts and circumstances presented herein constitute a federal question over which this Federal District Court exercises original jurisdiction under 28 USC Section 1331.

185. The avoidance of federal regulation by Defendant Orthogen International GmbH over Regenokine®, which it misrepresents to the public at large is a treatment plan as opposed to a regulated pharmaceutical, drug or modality, presents a potential threat to the health, safety and welfare of persons located within this District and throughout the United States.

186. The failure or refusal to date of FDA and CBER to assert administrative and regulatory control over Regenokine®,, to fail to undertake investigation and testing of Regenokine®,, and to impose its process under which approval to use Regenokine®, for treatmentof patients may be rejected,

approved or approved with conditions and exclusions, and to stay the use of Regenokine®, on patients pending the outcome of the administrative and regulatory process, constitutes non-compliance with the aforesaid statutory and regulatory requirements.

187. Orthogen's history of licensing for Regenokine®, one or more individuals not licensed to practice medicine is unacceptable and illegal under New York law in that Regenokine® constitutes the practice of medicine. Consequently, any license for Regenokine® issued to such medically unlicensed individual(s) is void ab initio rendering such License nugatory and meaningless without force or effect.

188. Plaintiffs Douglas Schottenstein, MD and Schottenstein Pain and Neuro, PLLC d/b/a NY Spine hereby demand judgment against Defendants Orthogen International GmbH ("Orthogen") and United States Food and Drug Administration ("FDA") that this United States District Court and not the Courts of Germany has jurisdiction over the controversies stated herein.

189. WHEREFORE, Plaintiffs Douglas Schottenstein, MD and Schottenstein Pain and Neuro, PLLC d/b/a NY Spine hereby demand judgment against Defendants Orthogen International GmbH ("Orthogen") and United States Food and Drug Administration ("FDA") declaring that

    a. FDA is required under applicable law and regulations to determine whether or not Regenokine® is a drug, pharmaceutical or other modality subject to its administrative oversight and regulation through its Center for Biologics Evaluation and Research ("CBER"),

b. that in the interest and protection of public health and safety, the use of Regenokine® on patients in the United States must be stayed pending the decision of FDA as to whether or not investigation and testing of Regenokine® and the imposition of the process to thoroughly review Regenokine® to determine whether it is rejected as a drug, pharmaceutical or modality for the treatment of patients or approved with or without specific conditions or limitations, and

c. that the use of Regenokine® on any patient constitutes the practice of medicine under New York law, which practice must be licensed, thereby rendering a Regenokine® License to an individual not licensed to practice medicine nugatory and meaningless, void ab initio, and without force or effect.

COUNT I
(TORTIOUS INTERFERENCE AGAINST THE ORTHOGEN DEFENDANTS)

190. Plaintiffs reincorporate the above paragraphs as if fully set forth herein.

191. On or about March 24, 2020, Orthogen in conspiracy with the Capla defendants and with specific intent to do so, wrongfully terminated the perennial License for the Regenokine® Program issued to plaintiff Dr. Schottenstein and defendant Capla, not on any "for cause" basis, but on the sole basis that the License was not being renewed.

192. At all times pertinent to this illegal action and the underlying conspiracy by and between the Orthogen defendants and the Capla defendants, Orthogen and the other Orthogen

defendants knew that that they were tortiously interfering with plaintiffs' economically advantageous relationship with the Capla defendants that would result in losses to plaintiffs in the tens of millions of dollars.

193. At some point, the Orthogen defendants commenced to conspire with the Capla defendants to interfere with and deny plaintiffs the benefits of their economic relationship with the Capla defendants, and to act fraudulently and deceitfully to cover up said conspiracy and prevent plaintiffs from taking action to challenge and remediate same.

194. Within days after the discontinuance of the Regenokine® Program License Agreement with Schottenstein and Capla, Orthogen in furtherance of the aforesaid conspiracy and its tortious interference entered into a new Regenokine® Program License Agreement with defendants Wasserman and Capla to the exclusion of plaintiffs, who were unjustly regarded by the Orthogen defendants as *persona non grata*.

195. In conspiracy with the other Orthogen defendants and the Capla defendants, defendant P. Wehling actively and knowingly engaged in fraudulent and deceitful communications with Dr. Schottenstein with the specific intent to mislead Dr. Schottenstein, prevent him from learning of the foregoing conspiracy, and cause him to withhold action challenging the License non-renewal and thereby lose the opportunity to remediate the damages willfully being caused.

196. Defendant Breidenbach actively conspired with the other Orthogen defendants and the Capla defendants with the express intent to interfere with plaintiffs' economically advantageous relationship with Capla, and through

fraudulent and deceitful actions and/or omissions to deprive plaintiffs of the revenues earned under that relationship.

197. Breidenbach joined in the conspiracy to disrupt the economically advantageous relationship that plaintiffs enjoyed with the Capla defendants, and thereafter participated in the fraudulent and deceitful conduct with the other Orthogen defendants to terminate that relationship and fulfill the objectives of the conspiracy by issuance of a new License to Wasserman and Capla and excluding plaintiffs without legal or factual justification.

198. Thereafter, the Orthogen defendants demanded that plaintiff Dr. Schottenstein transfer to defendants Capla and Wasserman the 3,500 patients that he had actively treated under the Regenokine® Program, thereby depriving Dr. Schottenstein of not only millions of dollars in revenue but also extraordinary damage to his professional reputation with these patients.

199. In furtherance of the foregoing conspiracy with the other Orthogen defendants and the Capla defendants, on August 3, 2022, defendant Niederau signed and delivered a letter to Dr. Schottenstein refusing to provide any know-how or services under the Regenokine® Program, stating "that there is no valid licensing agreement between you [Dr. Schottenstein] and ORTHOGEN," and demanding that Dr. Schottenstein refrain from any offer of the Regenokine® Program to his patients and to immediately take other specifically designated actions to disassociate from the Program.

200. In preparing and sending this letter to Dr. Schottenstein, defendant Niederau both advanced the conspiracy in which he had joined, acted knowingly with fraud and deceit, and fully

ratified the conspiracy between and among the Orthogen defendants and the Capla defendants and its goals.

201. The Orthogen defendants purposefully interfered with plaintiffs' economic advantage in the Schottenstein-Capla agreement by wrongful means and/or acted for the sole purpose of grievously harming plaintiffs.

202. In wholly disrupting and defeating plaintiffs' economic advantage as described above, the Orthogen defendants intentionally acted with fraud and deceit, engaged in multiple misrepresentations, and conspired with specific intent to accomplish their wrongful goals, thereby succeeding in accomplishing same.

203. The Orthogen defendants' acts were both scurrilous and outrageous and intentionally caused plaintiffs to incur compensatory damages in the amount of $129,356,404 and exemplary damages in the amount of $108,000,000.

204. WHEREFORE, plaintiffs Douglas Schottenstein, MD and Schottenstein Pain and Neuro, PLLC doing business as NY Spine, demand judgment against defendants Orthogen International GmbH, Prof. Dr. Peter Wehling, Nina Breidenbach, and Peter Niederau in the amounts of $129,356,404 in compensatory damages and $108,000,000 in punitive damages together with attorneys' fees, costs of suit, and such other and further relief as this Court may find equitable and just.

COUNT II
(FRAUD AND DECEIT WITH CIVIL CONSPIRACY AGAINST THE ORTHOGEN AND CAPLA DEFENDANTS AND CONVERSION, BREACH OF CONTRACT AGAINST CAPLA AND WASSERMAN)

205. Plaintiffs reincorporate the above paragraphs as if fully set forth herein.

206. On information and belief, there came a time when the Capla defendants conspired amongst themselves and with Orthogen and the other Orthogen defendantsto exclude plaintiffs from the right to practice under the Regenokine® Program License.

207. In doing so, both the Orthogen defendants and the Capla defendants acted with fraud and deceit deliberately shielding their activities from plaintiffs and making statements calculated to mislead plaintiffs thereby causing Dr. Schottenstein to believe that all was in order within the agreement with Capla.

208. In acting in this manner, the Orthogen defendants well knew that they were acting tortiously to interfere with the highly advantageous economic relationship by and between plaintiffs and Capla, and that their actions further constituted a breach of the fiduciary duties they owed to plaintiffs.

209. On information and belief, defendants Capla and Wasserman negotiated a new Regenokine® Program License for themselves with Orthogen to the exclusion of plaintiffs using fraudulent acts and statements to shield their acts as they proceeded to convert unto themselves the entire Regenokine® Program practice in which plaintiff Dr. Schottenstein owned at least 50%.

210. Capla and the other Capla defendants, employing fraud and deceit through their conspiracy with the Orthogen defendants,

also breached the agreement by and between Dr. Schottenstein and Capla as well as the implied covenant of good faith and fair dealing and their respective fiduciary duty and duties of loyalty to plaintiffs.

211. On or about March 24, 2020, defendant Orthogen acting through defendant Breidenbach, then Managing Director, and fully supported by defendant P. Wehling, issued a letter to Dr. Schottenstein and defendant Capla advising that the License under the Regenokine® Program was to be terminated by May 31st, 2020 on the basis of non-renewal in accordance with the June 1st, 2014 License Agreement. The letter did not refer to any for cause basis for the termination.

212. On information and belief this March 24, 2020 letter was issued to achieve the purpose of the conspiracy between the Orthogen defendants and the Capla defendants. Moreover, although not mentioned in this letter, on information and belief, the arrangement to issue a new Regenokine® ProgramLicense to defendant Capla and defendant Wasserman to the exclusion of plaintiffs had already been agreed upon.

213. The March 24, 2020 letter constituted a knowing, false, deceitful and illegal action by defendants Orthogen and Breidenbach, issued in breach of the controlling Side Letter Agreement dated July 9, 2014, and motivated by and with specific intent to further the conspiracy and achieve its goal of damaging plaintiffs.

214. Shortly after the receipt of the March 24, 2020 letter, defendants Capla and Y. Capla sent Dr. Schottenstein an intentionally fraudulent text message deceitfully and falsely confirming that they were pursuing a non-medical opportunity and deliberately withholding information that

they had negotiated a new Regenokine® Program License agreement with Orthogen to the exclusion of plaintiffs.

215. The purpose of this text message was to falsely assure plaintiffs that they had accepted the termination and to mislead plaintiff Dr. Schottenstein into believing that nothing had occurred to merit a challenge.

216. On information and belief, defendants Wasserman, J. Capla, T. Capla and Y. Capla conspired with Capla and the Orthogen defendants to exclude plaintiffs from the right to practice under the Regenokine® Program License.

217. In doing so, Defendants, individually and collectively, acted in violation of their fiduciary duty and/or duty of loyalty to plaintiffs, and with fraud and deceit deliberately shielding their activities from plaintiffs and making statements calculated to mislead plaintiffs thereby causing Dr. Schottenstein to believe that all was in order within the agreement with defendant Capla in order for these defendants to gain time for the conspiracy to succeed.

218. In conspiracy with the other Orthogen defendants and the Capla defendants, defendant P. Wehling actively and knowingly engaged in fraudulent and deceitful communications with Dr. Schottenstein with the specific intent to mislead Dr. Schottenstein, prevent him from learning of the foregoing conspiracy, and cause him to withhold action to challenge the License non-renewal and thereby sacrifice the opportunity to remediate the damages willfully being caused.

219. In this regard, P. Wehling deliberately, fraudulently and deceitfully misinformed Dr. Schottenstein that the non-renewal of the License was merely the result of a change in

Orthogen's internal policy to limit practice under the Regenokine® Program to German practitioners while Orthogen was engaging in discussions to sell all or a portion of the Regenokine® Program rights to third parties. P. Wehling also fraudulently and deceitfully misinformed Dr. Schottenstein that the License would be reissued to Capla and him promptly after the current negotiations were concluded.

220. On information and belief, defendant Breidenbach actively conspired with the other Orthogen defendants and the Capla defendants with the express intent to interfere with plaintiffs' economically advantageous relationship with Capla, and through fraudulent and deceitful actions and/or omissions to deprive plaintiffs of the revenues earned under that relationship.

221. In furtherance of the foregoing conspiracy, Breidenbach signed and sent to Dr. Schottenstein and Capla the March 24, 2020 non-renewal notice thereby discontinuing the Regenokine® Program License Agreement issued to them.

222. Defendant Breidenbach joined in the conspiracy to disrupt the economically advantageous relationship that plaintiffs enjoyed with the Capla defendants, and thereafter participated in the fraudulent and deceitful conduct with the other Orthogen defendants to terminate that relationship and fulfill the objectives of the conspiracy by issuance of a new License to Wasserman and Capla.

223. In furtherance of the foregoing conspiracy with the other Orthogen defendants and the Capla defendants, on August 3, 2022, defendant Niederau signed and delivered a letter to Dr. Schottenstein refusing to provide any know-how or services under the Regenokine® Program, stating "that there is no

valid licensing agreement between you [Dr. Schottenstein] and ORTHOGEN," and demanding that Dr. Schottenstein refrain from any offer of the Regenokine® Program to his patients and to immediately take other specifically designated actions to disassociate from the Program.

224. In preparing and sending this letter to Dr. Schottenstein, defendant Niederau both advanced the conspiracy in which he had joined, acted knowingly with fraud and deceit, and fully ratified the conspiracy between and among the Orthogen defendants and the Capla defendants.

225. Plaintiffs relied upon the fraudulent and deceitful acts and omissions of defendants and were deceived.

226. The foregoing actions have injured plaintiffs economically and in regard to their reputation concerning the Regenokine® Program patients they treated and within the medical community.

227. The conduct of defendants in this regard was scurrilous and outrageous meriting exemplary damages.

228. WHEREFORE, plaintiffs Douglas Schottenstein, MD and Schottenstein Pain and Neuro, PLLC doing business as NY Spine, demand judgment against defendants Orthogen International GmbH, Prof. Dr. Peter Wehling, Nina Breidenbach, Peter Niederau and against defendants Edward L. Capla, Judith J. Capla, MD, Tomas Capla, DDS, Yolanda Capla and Bradley Wasserman, MD, jointly and severally, in the amounts of $129,356,404 in compensatory damages and $108,000,000 in punitive damages together with attorneys' fees, costs of suit, and such other and further relief as this Court may find equitable and just.

COUNT III
(INJUNCTIVE RELIEF AGAINST THE ORTHOGEN DEFENDANTS)

229. Plaintiffs reincorporate the above paragraphs as if fully set forth herein.

230. By letter dated November 28, 2022 from legal counsel, Orthogen, first contended that the March 24, 2020 letter effectively terminated Dr. Schottenstein's License, a position that wholly ignores the admissions binding Orthogen that the Schottenstein License was never terminated and had been fully reinstated, then asserted that the reinstated License was terminated once again, this time for cause.

231. In that letter, defendant Orthogen through its legal counsel threatened to commence litigation against plaintiffs in the court of Dusseldorf, Germany.

232. Plaintiffs seek injunctive relief from this Court to stay defendant Orthogen and the other Orthogen defendants from commencing such litigation in Germany, considering that this case includes the United States Food and Drug Administration as a defendant in order to address and resolve the federal questions that underlie all claims asserted herein as well as the Orthogen defendants and the Capla defendants comprising all of the parties needed to resolve the claims set forth hereunder, and where this matter also addresses claims based upon tortious interference, fraud and deceit, breach of fiduciary duty, breach of the duty of loyalty, conspiracy, conversion,an accounting, unjust enrichment and constructive trust to remedy the wrongful acts that occurred within the jurisdiction of this Court.

233. The facts set forth in this Complaint demonstrate a likelihood of success for plaintiffs on the merits in that Orthogen issued the March 24, 2020 termination notice to Dr. Schottenstein not due to oversight or mistake, but with an intention to both evade federal regulatory jurisdiction as well as to tortiously interfere with the economically advantageous relationship with Capla that can no longer be ignored.

234. The Orthogen defendants and the Capla defendants conspired with fraud and deceit and with specific intent to damage plaintiffs economically and in their reputation.

235. The participation of the Orthogen defendants in that conspiracy enabled the tortious interference with the Schottenstein-Capla agreement and further enabled defendants Capla and Wasserman to convert the Regenokine® Program practice in which Dr. Schottenstein owned at least 50%.

236. Commencing an action in Germany will prevent plaintiffs from asserting the claims set forth in this Complaint against all parties regarding the federal questions asserted as well as the intricately entwined pendant claims and will further disrupt these proceedings thereby causing plaintiffs irreparable harm.

237. The Orthogen defendants will have a full and fair opportunity to litigate all of the issues posed in this Complaint and the further opportunity to assert a counterclaim if and as desired by them.

238. The proceeding in Germany will not afford plaintiffs the opportunity to assert their claims against Capla, Wasserman and the other Capla defendants nor to obtain an accounting or establish a constructive trust over the funds generated by the

Regenokine® Program Practice that Capla and Wasserman have converted. Under this analysis, the equities balance in favor of the plaintiffs to preserve the status quo while these issues are litigated.

239. WHEREFORE, plaintiffs Douglas Schottenstein, MD and Schottenstein Pain and Neuro, PLLC doing business as NY Spine, demand the issuance of a preliminary injunction barring defendants Orthogen International GmbH, Prof. Dr. Peter Wehling, Nina Breidenbach, and Peter Niederau or any one or more of them from initiating litigation in Germany against plaintiffs thereby requiring them to litigate all issues in this Court together with such other relief as this Court may deem necessary or just.

COUNT IV
(AGAINST DEFENDANT ORTHOGEN AND DEFENDANTS CAPLA AND WASSERMAN FOR UNJUST ENRICHMENT, AN ACCOUNTING AND IMPOSITION OF CONSTRUCTIVE TRUSTS)

240. Plaintiffs repeat the above allegations as if fully set forth herein.

241. Defendants Orthogen and Capla have each entered into separate confidential and/or fiduciary relationships with plaintiff Dr. Schottenstein.

242. Orthogen entered into this relationship with Dr. Schottenstein in or about 2012 in the form of a Regenokine® Program License Agreement with a 2-year renewable term, which License Agreement was renewed in or about June, 2014 and thereafter modified with a perennial term that required no renewals and could only be terminated for cause.

243. Commencing in or about 2012, Capla entered into an agreement with Dr. Schottenstein constituting a confidential and fiduciary relationship by reason of Capla's acceptance of a Regenokine® Program License designating him as Licensee No. 2 that was subordinate to and under the supervision of Dr. Schottenstein as Licensee No. 1, but was accompanied by their agreement regarding allocation of revenues to plaintiffs and payment of compensation to Capla and the other Capla defendants for the services they rendered.

244. Under the terms of the Regenokine® Program License Agreement, defendant Orthogen promised Dr. Schottenstein that he would enjoy the benefits of said Agreement and the revenue generated thereunder in accordance with the terms of that Agreement.

245. In accordance with their agreement concerning the conduct of the Regenokine® Program practice, Capla and Dr. Schottenstein entered into mutual promises with the other to conduct their activities thereunder in good faith and with recognition of their fiduciary duties each to the other.

246. Dr. Schottenstein expended money, labor and time both under the Regenokine® Program License Agreement with Orthogen, and in regard to the agreement with Capla. These expenditures benefitted both Orthogen and Capla within their respective agreements with Dr. Schottenstein, and these expenditures constituted a transfer of value to each of the aforesaid defendants in reliance by plaintiffs thereon.

247. On or about March 24, 2020, defendant Orthogen in conspiracy with the Capla defendants and with specific intent to do so, wrongfully terminated the perennial License for theRegenokine® Program issued to plaintiff Dr. Schottenstein and defendant Capla, not on any "for cause"

basis, but on the sole basis that the License was not being renewed.

248. At all times pertinent to this illegal action and the underlying conspiracy by and between the Orthogen defendants and the Capla defendants, Orthogen and the other Orthogen defendants knew that that they were tortiously interfering with plaintiffs' economically advantageous relationship with the Capla defendants that would result in losses to plaintiffs in the tens of millions of dollars.

249. At some point, the Orthogen defendants commenced to conspire with the Capla defendants to interfere with and deny plaintiffs the benefits of their economic relationship with the Capla defendants, and to act fraudulently and deceitfully to cover up said conspiracy and prevent plaintiffs from taking action to challenge and remediate same.

250. Within days after the discontinuance of theRegenokine® Program License Agreement with Schottenstein and Capla, Orthogen in furtherance of the aforesaid conspiracy and its tortious interference entered into a new Regenokine® Program License Agreement with defendants Wasserman and Capla to the exclusion of plaintiffs, who were unjustly regarded by the Orthogen defendants as *persona non grata*.

251. In taking the aforesaid actions, defendant Orthogen acted with fraud and deceit, and defendants Capla and Wasserman and the other Capla defendants breached their respective fiduciary duties and duties of loyalty by taking over and converting plaintiffs' interest in the Regenokine® Program practice.

252. The aforesaid respective acts of Orthogen and the other Orthogen defendants as well as Capla, Wasserman and the

other Capla defendants have caused plaintiffs to incur tens of millions in damages, which continue to grow each day, and have unjustly enriched Orthogen as well as Capla and Wasserman in that they have obtained and possessed value and revenues that in good conscience and equity rightfully belong to plaintiffs.

253. Moreover, despite defendant Orthogen maintaining a significant business presence in New York, on information and belief, it has failed and or refused to qualify to do business in New York or to maintain sufficient assets in this jurisdiction to satisfy the judgment arising from plaintiffs' claims hereunder. Furthermore, on information and belief, defendant Orthogen has entered into an arrangement with its parent, Orthogen AG, whereunder all funds received by defendant Orthogen are automatically swept into the account of Orthogen AG, thereby rendering those funds less available to satisfy the obligations of defendant Orthogen, including a judgment rendered against it hereunder.

254. The Orthogen defendants have exhibited a pattern of fraudulent, deceitful and otherwise outrageous tortious conduct as delineated in this Complaint giving rise to a high probability of compensatory and punitive damages being found against them.

255. In light of the foregoing, plaintiffs are further entitled to establish a constructive trust over all funds derived from the aforesaid Capla-Wasserman Regenokine® Program practice and/or any other such practice located within New York State that would otherwise be payable to defendant Orthogen as royalties or other fees in order to maintain these assets of the Orthogen defendants within the jurisdiction of this court and to satisfy the claims asserted against it herein.

256. Plaintiffs are further entitled to an accounting and to impose and establish a constructive trust over all assets, patient lists, treatment records and earnings of Capla, Wasserman and the other Capla defendants derived from the Regenokine® Program practice, in which they have and continue to be wrongly engaged and thereby unjustly enriched.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment which will:

DECLARE JURISDICTION over Orthogen, the administration and distribution of Regenokine® and provide US FDA oversight and/or approval in this United States District Court and not a Court of Foreign Jurisdiction;

ISSUE AN ACCOUNTING of all revenues, patients, procedures, records and royalty payments to Orthogen from and after May 31, 2020 to and through the current date and thereafter until further order of this Court, for

A CONSTRUCTIVE TRUST of same, and against defendant Orthogen for the establishment and imposition of a constructive trust for all funds derived from the aforesaid Capla-Wasserman Regenokine® Program practice and/or any other such practice located within New York State that would otherwise be payable to defendant Orthogen as royalties or other fees commencing on and after May 31, 2020 and continuing thereafter until further order of this Court; or

APPOINTMENT OF A RECEIVER Pertaining to the administration of Regenokine and profits derived from the same, while

PROHIBITING The administration of Regenokine® by non-licensed medical professionals pending US FDA approval;

PROHIBITING Defendants, individually and collectively, from unlawfully usurping business interests, interfering with patient-client privilege, usurping Plaintiffs' patients, proprietary interests, money and other resources from Plaintiff

ENJOINING Orthogen from licensure, administration and distribution of Regenokine® without US FDA oversight and/or approval;

AWARD, on Counts I, II and/or IV, (TORTIOUS INTERFERENCE AGAINST THE ORTHOGEN DEFENDANTS), judgment against defendants Orthogen International GmbH, Prof. Dr. Peter Wehling, Nina Breidenbach, and Peter Niederau in the amounts of $129,356,404 in compensatory damages and $108,000,000 in punitive damages together with attorneys' fees, costs of suit, and such other and further relief as this Court may find equitable and just.

AWARD all costs, including costs and attorneys' fees, and the costs of prosecuting this action to the fullest extent allowed by law.

All together with such other and further and additional relief as this Court may deem just and proper.

THE REST OF THIS PAGE INTENTIONALLY LEFT BLANK

DATED AT Huntington, N.Y.
December 27, 2022

/S/

RICHARD BRUCE ROSENTHAL (RR1834)
CO-COUNSEL FOR PLAINTIFFS
545 E. JERICHO TURNPIKE
HUNTINGTON STATION, NY 11746
(631) 629 - 8111

JEFFREY A. DONNER
CO-COUNSEL FOR PLAINTIFFS
708 HIGHWAY 35 SOUTH
NEPTUNE, NEW JERSEY 07753
(732) 578-8530

CORY H. MORRIS (CM 5225)
THE LAW OFFICES OF CORY H. MORRIS
Co-Counsel for Plaintiffs
135 Pinelawn Road, Suite 250s
Melville NY 11747
(631) 450–2515

INDEPENDENT VERIFICATION

State of New York
New York County } *ss*:

Douglas Schottenstein, MD, a licensed medical doctor duly affirming under the penalty of perjury deposes and says that I am the Plaintiff(s) filing this Verified Complaint; that I have read the foregoing Verified Complaint and know the contents thereof; that the same is true to deponent's own knowledge, except as to the matters therein stated to be alleged on information and belief.

Duly affirmed under penalty of
perjury on December 27, 2022

/S/

Douglas Schottenstein